



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/087,198 | 03/01/2002 | Daryl Real | 54071J328-US1 | 8576 |

7590 06/20/2003

DARBY & DARBY P.C.
805 Third Avenue
New York, NY 10022

[REDACTED]

JAGOE, DONNA A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1614 | 14 |

DATE MAILED: 06/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|---------------------------------------|---------------------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/087,198 Examiner Donna Jagoe | REAL ET AL. Art Unit 1614 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 10 April 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-15 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>12</u> . | 6) <input type="checkbox"/> Other: _____ . |

Claims 1-15 are pending in this application.

Specification

The disclosure is objected to because it contains embedded hyperlinks and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See pages 4 and 5 of the instant specification.

Response to Declaration

The declaration under 37 CFR 1.132 filed 10 April 2003 is sufficient to overcome the rejection of claims 1-15 based upon 35 U.S.C. §102(a).

Response to Arguments

Applicant's arguments, see pages 2-3, filed April 10, 2003, with respect to Nelssen et al. The Swine Update, Spring 2001 have been fully considered and are persuasive. The rejection of claims 1-15 under 35 U.S.C. §102(a) has been withdrawn.

The rejection made in paper number 9 over Arthington under 35 U.S.C. §103 is maintained and is hereby repeated. Regarding applicant's remarks that the composition is drawn to finishing pigs rather than during gestation, lactation, breeding and/or prebreeding, as stated in the office action, it would have been obvious to employ the combination of L-carnitine and chromium picolinate since Arthington teaches that L-carnitine can increase lean gain potential by increasing the amount of energy a pig

receives during an energy dependent phase of growth and chromium picolinate increases the uptake of amino acids at the cellular level, thus increasing energy for growth and to optimize muscle development. It would have been obvious to employ the combination motivated by the need of a sow that is farrowing, gestating or lactating for improved uptake of amino acids to improve litter size and milk production.

The Examiner is in agreement with the persuasive remarks submitted concerning the outstanding 35 U.S.C. §103 rejection made in paper number 9 in view of which the rejection is hereby withdrawn.

Applicant's arguments, see page 5, filed 10 April 2003, with respect to the rejection of claims 1-15 under 35 U.S.C. §103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Lindeman et al. (#1 from IDS dated 12 June 2002), and Kansas State University Research Foundation WO 98/24328 A1 (#1 from IDS dated 1 April 2003) over claims 1-15 under 35 U.S.C. §103(a).

The claims are drawn to methods and compositions for enhancing reproductive performance of a sow comprising feeding a sow during gestation, lactation, breeding and/or prebreeding L-carnitine or a salt thereof and chromium picolinate, chromium nicotinate or chromium tripicolinate and a carrier.

Kansas State University teach administration of carnitine to sows during the period of gestation or during both gestation and lactation periods. L-carnitine or L-

carnitine salts are added to swine feed formulation in the amount of from 5 to about 5000 ppm (see abstract).

Kansas State University does not teach combination of L-carnitine with chromium picolinate.

Lindemann et al. teach administration of chromium picolinate through breeding and reproduction in an amount of from 0 to 1000 ppb. The data demonstrates positive responses to supplementing the diet of reproducing swine with chromium picolinate.

Lindemann et al. does not teach combination of chromium picolinate with L-carnitine.

As stated in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980):

It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Susi*, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960). As this court explained in *Crockett*, the idea of combining them flows logically from their having been individually taught in the prior art.

Therefore, it would have been *prima facie* obvious to combine L-carnitine and chromium co-jointly in a formulation to enhance sow reproductive performance.

To overcome such rejections applicant must provide evidence of synergism, i.e. evidence that more than the expected additive effect occurs when components are combined. In reviewing the data in the instant specification, it does not appear that synergism occurred in the data that relates to the first parity with the exception of the % estrus by d 7 and % estrus by d 18. In the second parity, there may be evidence of

synergism in the data wherein the sows were bred by day 18, farrowed, first service farrow rate % and percentage of weaned parity sows that farrowed in parity 2 (page 15 of the instant specification). There does not seem to be evidence of an additive effect for the data relating to total pigs born, born alive, stillborn and mummies (page 16 of the instant specification).

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hagen et al. (#4 of IDS dated 11/29/02) in view of Musser et al. J. Anim. Sci. 1999 77:3289-3295.

The claims are drawn to methods and compositions for enhancing reproductive performance of a sow comprising feeding a sow during gestation, lactation, breeding and/or prebreeding L-carnitine or a salt thereof and chromium picolinate, chromium nicotinate or chromium tripicolinate and a carrier.

Hagen et al. teach dietary supplementation of 200 ppb of chromium tripicolinate has a positive impact on sow productivity, allows greater animal output by allowing the sow to breed by 7 days post weaning, the number of pigs born alive and weaned and the sow mortality (page 59, column 1, 2nd and 3rd paragraphs), thus improving litter size and rebreeding efficiency.

Hagen et al. does not teach administration of L-carnitine.

Musser et al. teach administration of L-carnitine 100 mg/day during gestation and 50 ppm during lactation. Supplementation with L-carnitine during gestation increased both total litter, pig birth weight and weight at weaning. Musser et al. discloses that

feeding L-carnitine during gestation and lactation increased the subsequent number of pigs born alive and increased litter weight at birth and weaning (see abstract).

Musser et al. does not teach administration of chromium.

As stated in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980):

It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Susi*, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960). As this court explained in Crockett, the idea of combining them flows logically from their having been individually taught in the prior art.

Therefore, it would have been *prima facie* obvious to combine L-carnitine and chromium co-jointly in a formulation to enhance sow reproductive performance.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (703) 306-5826. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 872-9307 for After Final communications.

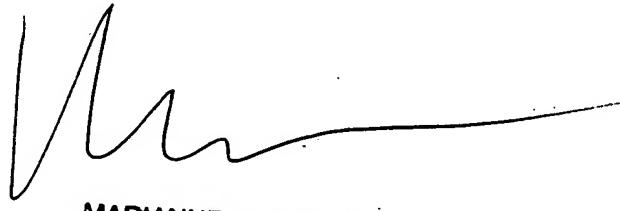
Art Unit: 1614

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Donna Jagoe
Patent Examiner
Art Unit 1614

dj
June 17, 2003



MARIANNE C. SEIDEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600